

Appl. No. : 09/988,850
Filed : November 19, 2001

REMARKS

Claims 1-6 have been withdrawn from consideration as being directed to a non-elected invention. Claim 7 has been amended by this paper and Claims 8-28 have been added by this Amendment. Hence, by this paper, Claims 7-28 are presented for further examination.

In the Office Action mailed September 23, 2003, the Examiner set forth the basis for a restriction to one of five groups of claims under 35 U.S.C. § 121. The Examiner made reference to a telephone conversation with Donald Bollella on August 8, 2003, during which a provisional election was made with traverse to prosecute the invention of Group V, Claim 7. Applicant hereby affirms this election.

In the Office Action mailed September 23, 2003, the Examiner stated that "Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. § 119(e). The Examiner acknowledged Applicant's claim for domestic priority under 35 U.S.C. § 119(e), but the Examiner stated that "the provisional application upon which priority is claimed fails to provide adequate support under 35 U.S.C. § 112 for Claim 7 of this Application."

In response, Applicant advises that it will continue to claim priority because the Applicant disagrees that there is no support for the claims as presented herein. As the Examiner noted, "the disclosure of the invention in the parent and in the later filed application must be sufficient to comply with the requirements of the first paragraph of 35 U.S.C. § 112." (emphasis added) Applicant asserts that there is support in either the priority application, or the instant utility application, but certainly the combination does provide the support necessary to comply with the requirements of the first paragraph of 35 U.S.C. § 112.

In addition, Applicant continues to maintain the claim for priority in order to obtain the benefit of the earlier filing date both for the claims that have been added by this amendment, as well as those which may be added in the future and for those to be filed in continuing or divisional applications. In view of the above, Applicant submits that it has complied with the conditions provided for receiving the benefit of the earlier filing date under 35 U.S.C. § 1.9(e).

In the Office Action mailed September 23, 2003, the Examiner noted that "the listing of references in the specification is not a proper Information Disclosure Statement." The Examiner noted that the list of prior art must be submitted in a separate paper. He further stated that

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“unless the references have been cited by the Examiner in form PTO-892, they have not been considered.”

Applicant advises that an Information Disclosure Statement will be submitted which satisfies the requirements of 37 C.F.R. § 1.98(d) and which will include those prior art references identified in the specification which have not been cited by the Examiner on form PTO-892.

In the Office Action mailed September 23, 2003, the Examiner objected to the abstract of the disclosure “because in line 2 of the abstract, the phrase ‘a methods’ is ambiguous.” The Examiner required correction. By this paper, Applicant has amended the abstract to correct this typographical error.

In the Office Action mailed September 23, 2003, Claim 7 was rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point and distinctly claim the subject matter which Applicant regards as the invention. In particular, the Examiner referred to the last line of Claim 7 wherein the term “a capture zone” was said to be confusing. In response, Applicant has amended Claim 7 to define “a first capture zone” and “a second capture zone”. In view of this, Applicant submits that the basis for the rejection with respect to that term has been removed.

In addition, the Examiner stated that the term “associated with” in Claim 7 is a relative term which renders the claim indefinite. Accordingly, Applicant has amended Claim 7 to replace the term “associated with” with “in proximity to”. Applicant submits that this amendment overcomes the basis for rejection of Claim 7 as asserted in paragraph 12 of the instant Office Action. Accordingly, Applicant submits that the rejection under 35 U.S.C. § 112, second paragraph, has been overcome and respectfully requests that the Examiner withdraw this rejection.

In the Office Action mailed September 23, 2003, the Examiner rejected Claim 7 under 35 U.S.C. § 102(b) as being anticipated by Anderson, et al., (U.S. Patent No. 5,922,591 hereinafter referred to as “Anderson”). Among other things, the Examiner stated that Anderson teaches an apparatus comprising “... a first and second mixing chamber (hybridization, reaction chambers) with inlet ports (Col. 2, lines 20-39, 54-60, Col 21, lines 22-24), and a first (analytical chamber with an oligonucleotide array) and second (microcapillary electrophoresis device) detection chamber (Col. 24, lines 5-20).

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It appears that the Examiner's objections are directed toward the subject matter illustrated in Fig. 3, as described at the indicated locations in Col 21 and Col. 24. In particular, Applicant notes that the subject matter referred to with regard to Col. 2, lines 20-39, and 54-60 does not define a "mixing chamber". Those portions of Anderson do make reference to a reaction chamber, and the subject matter referred to in Col.'s 21 and 24 also addresses "reaction chambers". In particular, at Col. 22, lines 49-51, Anderson states that the "schematic representation of the device in Fig. 3 shows a device that comprises several reaction chambers arranged in a serial geometry." Applicant submits that the Examiner has attempted to characterize these various reaction chambers such that some define the claimed mixing chambers while other define the detection chambers. However, Applicant has found no teaching in the Anderson reference which discloses the mixing chambers and detection chambers as set forth in Applicant's Claim 7.

Furthermore, as was noted in Anderson at Col. 22, lines 49-53, the reaction chambers disclosed there are "arranged in a serial geometry." Thus, each chamber is respectively connected to the chambers which immediately precede and immediately follow that chamber. In contrast, Applicant's Claim 7 defines a first mixing chamber "in direct fluid communication with said separation chamber." Likewise, the claim defines a second mixing chamber "in direct fluid communication with said separation chamber and not in direct fluid communication with said first mixing chamber". There is simply no teaching, nor is there any suggestion of such a configuration of mixing and separation chambers set forth in Anderson.

Furthermore, Applicant's Claim 7 defines "a first detection chamber in direct fluid communication with said first mixing chamber," as well as "a second detection chamber in direct fluid communication with said second mixing chamber". Even if Anderson did disclose detection chambers, they would be connection in a serial arrangement, and not each be "in direct fluid communication" with their associated mixing chamber. Applicant submits that such a structure, as set forth in Applicant's Claim 7, is neither taught nor would it have been made obvious by Anderson. Accordingly, Applicant respectfully submits that Claim 7 defines subject matter that is patentable over the art of record.

In the Office Action mailed September 23, 2003, the Examiner rejected Claim 7 under 35 U.S.C. § 103(a) as being unpatentable over Virtanen (U.S. Patent No. 6,030,581, hereinafter

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referred to as "Virtanen") in view of Burd (U.S. Patent No. 5,061,381, hereinafter referred to as "Burd").

The Examiner indicates that Virtanen discloses a number of things including a "separation chamber", which the Examiner indicates is the analyte separation sector identified at 17 in Fig. 2A. The Examiner also indicates that a filter means is disclosed, however there is no indication provided by the Examiner as to where in the prior art this is described or shown. The Examiner additionally identifies a "mixing chamber" as the sample preparation sector 15 in Fig. 2A. This would indicate that the mixing chamber 15 would be in fluid communication with the separation chamber 17. The Examiner also identifies a "first detection chamber" which he indicates is the assay site 19 of Fig. 2A. The Examiner indicates that this assay site 19 is in fluid communication with the first mixing chamber as well as with a second detection chamber which would appear to be the DNA test chamber of Fig. 2B.

Based on the above designation of components, Applicant notes that the separation chamber 17 of Fig. 2A is interposed between the mixing chamber 15 and detection chamber 19 in Fig. 2A. Thus, Fig. 2A and the associated text in the patent do not teach a detection chamber 19 being in direct fluid communication with a mixing chamber 15. Rather, any fluid communication would necessarily travel through the separation chamber 17.

The Examiner notes that Virtanen "does not teach that the feature of a second mixing chamber with the second detection chamber being in fluid communication with the second mixing chamber. Instead, Virtanen teaches a second separation chamber, with the second detection chamber being in fluid communication with the second separation chamber (Fig. 2b)". Interestingly, Fig. 2B also does not show a mixing chamber (the "sample prep." channel according to the Examiner's characterization) in direct fluid communication with the separation chamber (the "sample sep." chambers according to the Examiner's characterization). Furthermore, there is no direct fluid communication taught between any detection chamber (the "immuno-assay" chamber according to the Examiner's characterization) and any mixing chamber.

Fig. 2B does show two sample separation chambers as apparently being interconnected, with each chamber also directly connected to other chambers which one may arguably characterize as detection chambers. However, there is no teaching or suggestion of the relocation of the mixing chamber (sample prep. of Fig. 2B) so as to be connected between the sample

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separation chambers and the immuno-assay or DNA test chambers of Fig. 2B. Absent such a modification, the components would not and could not be in direct fluid communication with those structures as presented in Applicant's Claim 7.

The Examiner refers to Burd as providing teachings whereby "it will be obvious to provide a second mixing chamber in fluid communication with the separation chamber and the second detection chamber in the method of Virtanen in order to allow combinations with different reagents or dilutants in isolated separation chambers." However, if one were to provide this second mixing chamber ("sample prep." of Figs. 2A or 2B of Virtanen) in order to accomplish the method of Virtanen, the structure would still not provide the direct fluid communication between the mixing chamber and the separation chamber and between the detection chamber and the mixing chamber, as defined in Applicant's Claim 7. There simply is neither any teaching nor suggestion in either Burd or Virtanen which would encourage one of skill in the art to make the significant mental gymnastics necessary to relocate the structures set forth in Virtanen Figs. 1-4 and to also combine teachings of Burd in order to create the structure as defined in Applicant's Claim 7.

In view of the above, Applicant respectfully submits that Claim 7 defines subject matter which is patentable over the art of record. Furthermore, Applicant submits that newly added independent Claim 20 also includes similar limitations which define subject matter which is patentable over the art of record. In addition, Applicant respectfully submits that Claims 8-19 and 21-28, which each depend from one of Claims 7 and 20 also define subject matter which is patentable over the art of record for at least the reasons set forth above.

In view of the forgoing, Applicant respectfully submits that Claims 7-28, as presented herein, define subject matter which is patentable over the art of record. Accordingly, Applicant respectfully submits that Claims 7-28 are now in condition for immediate allowance and such prompt allowance of the same is respectfully requested.

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CONCLUSION

The Applicant has endeavored to address all of the concerns of the Examiner in view of the recent Office Action directed to the above-identified application. Accordingly, amendments to the claims, the reasons therefor and arguments in support of the patentability of the pending claims are presented above. Any claim amendments which are not specifically discussed in the above remarks are made to improve the clarity of claim language, to correct grammatical mistakes or ambiguities, and to otherwise improve the capacity of the claims to particularly and distinctly point out the invention to those of skill in the art.

In light of the above amendments and remarks, reconsideration and withdrawal of the outstanding rejections is specifically requested. If the Examiner finds any remaining impediment to the prompt allowance of these claims that could be clarified with a telephone conference, the Examiner is respectfully requested to initiate the same with the undersigned.

Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

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Dated: 3/22/04

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